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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,283	11/13/2001	Elliott Farber	14358-316	3855
24633	7590	05/04/2005	EXAMINER	
HOGAN & HARTSON LLP IP GROUP, COLUMBIA SQUARE 555 THIRTEENTH STREET, N.W. WASHINGTON, DC 20004			SHARAREH, SHAHNAM J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/991,283		FARBER, ELLIOTT	
	<b>Examiner</b>		<b>Art Unit</b>	
	Shahnam Sharareh		1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,9-145,148-164 and 167-179 is/are pending in the application.
- 4a) Of the above claim(s) 22-136,151-158,174,176 and 178 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,6,12-21,139,140,160,161 and 170-173 is/are allowed.
- 6) ☒ Claim(s) 1-4,9-11,159,162-164,169, 175 and 179 is/are rejected.
- 7) ☒ Claim(s) 5,6,12-21,137-145,148-150,160,161,167,168,170-173 and 177 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/28/05</u>   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Amendment filed on December 03, 2004 has been entered. Claims 1-6, 9-145, 148-164, 167-179 are pending. Claims 1-6, 9-21, 137-150, 159-173, 175, 177, 179 read on the elected species. Claims 22-136, 151-158 are withdrawn from further consideration as being drawn to nonelected species.

Newly submitted claim 174, 176, 178 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly added claim is directed to a distinct invention which is related as a product and process of using the product. Here, the product as claimed can be used in a materially different process of using that product. Thus, the restriction is proper between said product and method of using. (MPEP 806.05(I)).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 174, 176, 179 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP 821.03.

This application contains claim 22-136, 151-158, 174, 176, 179 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any rejection that is not addressed in this Office Action is considered obviated in view of the Amended claims and the Terminal Disclaimer.

***Allowable Subject Matter***

2. Claims 5-6, 12-21, 139-140, 160-161, 170-173 are allowed because they are free of art and there is not motivation in the art to combine to use a composition containing allantoin being stable in a pH range of 3-6, the acidic wax of claim 5 and the anionic surfactant instantly taught for treating Epidermolysis Bullosa.

Claims 5-6, 12-21, 139-140, 160-161, 170-173 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-4, 9-11, 159, 162-164, 169-171, 175, 179 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroda et al JP 58-140013 (translated copy) in view of Brust et al (Dermatol Nur, 1996, Apr; 8(2): 81-9) and Magraf et al (Archives of Surgery, 1977; 112 (6): 699-704).

The instant claims are directed to methods of treating epidermolysis bullosa comprising administering an oil-in-water emulsion comprising allantoin, an acidic wax, an anionic emulsifier wherein allantoin stays stable in pH ranges of about 3-6. The instant claim 11 further requires the composition to contain at least one ingredient such as butylene glycol, cetyl alcohol, stearyl alcohol.

Kuroda et al teaches methods of applying a composition for treatment of burns and ulcers wherein the composition comprises allantoin, an anionic emulsifier, a wax, and an emollient such as cetyl alcohol or stearyl alcohol. (entire pages 2-4). The allantoin in Kuroda's compositions has prolonged stability of about 90 days when pH levels of the composition is adjusted below 5.5 (translated copy, page 2, 2<sup>nd</sup> and 3<sup>rd</sup> paragraph; table 2, page 6). The waxes of Kuroda include paraffin and Vaseline. Kuroda states that emulsion preparations such as ointments and creams may contain suitable anionic surfactants such as sodium alkylsulfates (translated copy, page 3, 1<sup>st</sup> paragraph). Thus, Kuroda's compositions meet the wax, anionic emulsifier and stability requirement of the instantly employed compositions.

Kuroda states that allantoin is an old compound, which is commonly used for treatment of various skin ailments such as, cuts, burns, as well as, inflammatory skin conditions including eczema (see translated copy page 2, 1<sup>st</sup> paragraph). Kuroda teaches all elements of the instant method claims except it does not specifically teach treating skin conditions such as epidermolysis bullosa and its use with corticosteroids.

Brust is merely used to show that epidermolysis bullosa manifests itself in the form of various types of skin wounds such as ulcers and blisters. Accordingly, supportive care of such skin wounds with suitable ingredients would have improved the patient's complications. (abstract, pages 83-85).

Magraf teaches the therapeutic benefits of allantoin in treating necrotic tissues (abstract). Magraf teaches that allantoin stimulates the growth of healthy tissue and debris necrotic tissue (see page 699, 1<sup>st</sup> col, 2<sup>nd</sup> paragraph). Magraf teaches the

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efficacy of allantoin containing cream in treating diabetic ulcers in 92 patients (see page 701, table 3; page 702, fig 3). Magraf acknowledges the use of corticosteroids in treatment of vascular skin ulcer (page 703, 2<sup>nd</sup> paragraph). Magraf further states that the vehicle of any topical agent plays a paramount role on the end clinical outcome (see page 704, 3<sup>rd</sup> paragraph). Accordingly, the use of allantoin for treatment of inflammatory skin conditions and ulcers is well recognized in the art.

Although Kurado fails to specifically teach the use of his allantoin containing composition for treatment of epidermolysis bullosa, it would have been obvious to one of ordinary skill in the art at the time of invention to use Kurado composition to improve the recovery of any skin suffering from ulcerogenic skin conditions including epidermolysis bullosa, because as taught by Burst, epidermolysis bullosa is manifested by skin ulcers/wounds and wound care provides an effective therapeutic approach for such condition.

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in improving the skin using allantoin as taught by Kuroda and Magraf, Bar-On, and Brust the ordinary skill in the art would have had a reasonable expectation to succeed in stimulating the growth of healthy tissues in such ulcers using the effective delivery formulations of Kurado, because allantoin is well described to stimulate the growth of healthy tissue for such conditions. Finally, using an adjunct corticosteroid regimen with allantoin formulation in treating ulcerated tissue would have also been obvious, because as taught by Magraf, the ordinary artisan would have had a reasonable expectation of observing cumulative therapeutic effect.

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4. Claims 137-138, 141-145, 148-150, 167-168, 177 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroda et al JP 58-140013 (translated copy) in view of Brust et al (Dermatol Nur, 1996, Apr; 8(2): 81-9) and Magraf et al (Archives of Surgery, 1977; 112 (6): 699-704) and Grollier et al US Patent 4,767,618.

The instant claims are essentially the same as the previously rejected claims except that the compositions employed by the instant claims also include carbohydrate polymers.

The teachings of Kuroda, Brust and Magraf are disclosed above. Their combined teachings fail to provide for the use of carbohydrate polymers.

Grollier provides of for the use of various carbohydrate thickeners such as guar gum, cellulose derivatives, etc. (col 5, lines 48-65). Grollier also suggests the use of suitable anionic surfactants such as sodium lauryl sulfate as emulsifying agents (see col 6, lines 5-13), lanolin oil, and cod liver oil as the oil phase (see col 5, line 27-30; col 6, line 40-41), propylene glycol or cetyl alcohol as solvents (col 5, lines 5-12; col 16, lines 30-35), perfume of choice, anti-inflammatory and antiseptic such as allantoin (col 16, line 34-35), a pH modifier, antioxidants such as butyl hydroxyanisole, and preservative agents such as methyl parahydroxybenzoate (methylparaban, see RN 99-76-3), or propyl parahydroxy benzoate (propylparaben, see RN 94-13-3) (see col 6, lines 56-60; col 14, lines 20-23). Grollier compositions are essentially in the form of emulsions (col 7, lines 9-21).

Accordingly, since it has been held that the selection of known material based on its suitability for its intended use supported a *prima facie* obviousness determination in

*Sinclair & Carroll co. V. Interchemcial Corp.*, 325 U.S. 327, 65 USPQ 297 (1945), it would have been obvious to one of ordinary skill in the art at the time of invention to further add suitable topical ingredients including any art equivalent carbohydrate thickeners to the emulsions of Kuroda, because the ordinary skill in the art would have had a reasonable expectation of success in improving the properties of such emulsions for its skin care and further apply such formulations to epidermolysis bullosa associated skin complications.

### ***Conclusion***

5. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

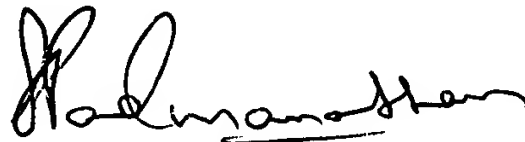
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnaz Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**